IN THE UNITED STATES DISTRICT COURT FOR THE DISTRICT OF DELAWARE

HUMAN GENOME SCIENCES, INC.,

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Plaintiff,

v. : C. A. No. 07-526-SLR-MPT

AMGEN, INC. and IMMUNEX CORP.,

Defendants.

MEMORANDUM ORDER

This is a patent case. Human Genome Sciences, Inc. ("HGS") filed this action against Immunex Corp. and Amgen, Inc. (collectively, "Immunex")¹ under 35 U.S.C. § 146 "to review the judgement entered July 27, 2007 by the Board of Patent Appeals and Interferences ('the Board') of the United States Patent and Trademark Office ('PTO') in Interference No. 105,381 ('the '381 Interference')."² At the Fed. R. Civ. P. 16 scheduling conference, a dispute arose concerning the court's scope of review and, relatedly, what discovery is appropriate in this matter. The parties submitted their competing arguments by letter to the court.³ This is the court's determination of the issues raised in those letters.

BACKGROUND

An interference is an *inter partes* administrative proceeding to determine which party first invented the subject matter of the interference as defined by the

¹ Immunex is a wholly-owned subsidiary of Amgen, Inc. See D.I. 22 at 1.

² D.I. 1, ¶ 1. (Complaint). In its answer and counterclaims, Immunex also challenges certain of the Board's determinations which were adverse to Immunex. See D.I. 13.

³ D.I. 22; D.I. 24.

interference "count." An interference is generally conducted in two phases, a motions phase and a priority phase. During the motions phase, the parties may submit various motions, including those for judgment (e.g., patentability based on enablement, written description, etc.) which, if granted, may terminate the interference in the movant's favor. Absent such judgment, the interference may continue to the priority phase during which the parties may submit motions and evidence to show they were the first to invent the subject matter of the interference.

BACKGROUND

The '381 Interference was between Jian Ni, Renier L. Gentz, Guo-Liang Yu, and Craig A. Rosen (collectively, "Ni"), on one side, and Charles Rauch and Henning Walczak (collectively, "Rauch"), on the other side. The Board determined

⁴ See D.I. 22, Ex. D at 3:11-14 (Decision - Order to Show Cause) ("An interference is a proceeding to assist the Director in making a determination whether an involved application should issue as a patent." (citing *Karim v. Jobson*, Interference 105,376, Paper 99, p. 7 (BPAI, February 28, 2007), http://www.uspto.gov/web/offices/dcom/bpai/its/105376-99.pdf)); 37 C.F.R. § 41.201 ("Count means the Board's description of the interfering subject matter that sets the scope of admissible proofs on priority.").

See D.I. 22, Ex. G at 2:8-3:2 (Decision - Rehearing Bd.R. 125(c)) ("Interferences are typically conducted in two phases: a first phase, often referred to as the 'motions phase,' and a second phase, the 'priority phase.' During the first phase adjustments may be made to the initial conditions of the interference by filing certain motions. These motions include, but are not limited to, challenging (1) the existence of the interference (no interference-in-fact), (2) the appropriateness of the count or counts (add or substitute counts), (3) the claims at risk in the interference (claim correspondence), (4) the patentability of involved claims, and (5) the constructive reduction to practice date of the subject matter of the count (according or attacking priority benefit). The first phase concludes with a decision on motions. The decision sets the conditions of the interference for the priority phase. These conditions include the count or counts (which govern the scope of the proofs which may be submitted to prove priority), the dates which the junior party must prove in order to prevail on priority, and the claims which will be lost in the event of an adverse judgment on priority. During the priority phase, the parties attempt to prove priority in the context of the conditions established as a result of the motions phase. The parties may attempt to prove an earlier actual reduction to practice, an earlier conception of the invention coupled with diligence to a later reduction to practice, and/or derivation.").

⁶ See, e.g., Karim, Interference 105,376, at 6 ("Under post-1984 practice, sometimes an interference can be resolved on the basis of unpatentability without any need to reach priority." (citing Berman v. Housey, 291 F.3d 1345 (Fed. Cir. 2002)).

Ni to be the junior party and Rauch to be the senior party.⁷ It also found Ni's real party-in-interest to be HGS and Rauch's real party-in-interest to be Immunex.⁸

HGS was involved in the interference on the basis of its application 10/005,842 ("the '842 application"), filed December 7, 2001. For the purposes of priority, the Board found the '842 application was accorded benefit of the March 17, 1998 filing date of application 09/042,583 ("the '583 application").

Immunex was involved in the interference on the basis of U.S. Patent No. 6,642,358 ("the '358 patent"), issued November 4, 2003, from application 09/578,392 ("the '392 application"), filed May 25, 2000. For priority purposes, the Board accorded the '392 application the benefit of the June 26, 1997 filing date of application 08/883,036 ("the '036 application"), which issued on June 6, 2000 as U.S. Patent No. 6,072,047 ("the '047 patent"). 10

The subject matter of the '381 Interference was defined by a single count ("Count 1") directed to a tumor necrosis factor receptor ("TNFR") family polypeptide

⁷ See D.I. 22, Ex. C at 3:4-5; 3:12 (DECISION-MOTIONS-Bd.R. 125(a)). Pursuant to 37 C.F.R. § 41.201: "Senior party means the party entitled to the presumption under § 41.207(a)(1) that it is the prior inventor. Any other party is a junior party."

⁸ D.I. 22, Ex. C at 3:11; 3:20. Although the Board refers to "Ni" and "Rauch" in its decision on the parties' motions, for clarity in this opinion, the court will refer to the interference parties, Ni and Rauch, by their respective real parties-in-interest, HGS and Immunex, respectively.

⁹ D.I. 22, Ex. C at 3:6-10; 37 C.F.R. § 41.201 ("Accord benefit means Board recognition that a patent application provides a proper constructive reduction to practice under 35 U.S.C. 102(g)(1).").

¹⁰ D.I. 22, Ex. C at 3:13-19. In its "Findings of Fact," the Board states that the '358 patent issued on November 4, 2005. D.I. 22, Ex. C at 3:14. In its discussion of Immunex's substantive motion 3, it recites a November 4, 2003 issue-date. D.I. 22, Ex. C at 29:11. According to the face of the patent, the 2003 date is correct.

called TRAIL Receptor-2 ("TR-2").¹¹ HGS' involved claims¹² were claims 35, 36, 38-45, 47-54, 56-61, 75, 83, 92, 99, 100, 102-109, 111-116, 127-133, 168-178, and 180-203.¹³ Immunex's involved claims were claims 1, 4-6, 8-11, 17-19, 26-28, 34, 37, 38, and 40.¹⁴ During the motions phase of the '381 Interference, the parties submitted various motions upon which the Board ruled in its March 26, 2007 decision, discussed below.¹⁵

In HGS' substantive motion 1, it sought to redefine the scope of the interference by substituting its proposed count 2 for Count 1, which proposal would add the limitation "or induces apoptosis" as an alternative to the limitation "binds TRIAL." The Board denied that motion. ¹⁷

In HGS' substantive motion 2, it sought to be accorded benefit for the purpose of priority the March 17, 1997 and July 29, 1997 filing dates of its earlier filed provisional applications 60/040,846 ("the '846 application") and 60/054,21 ("the '021 application"), respectively, as to Count 1, and as contingent on the grant of its

¹¹ D.I. 22 at 2 (citing *id.*, Ex. C at 3:22-4:4 ("Count 1 is 'Claim 6 of U.S. Patent 6,642,358". . . . Claim 6 of the '358 patent, written in independent form, reads: 'A purified TRAIL-R polypeptide comprising an amino acid sequence that is at least 90% identical to the amino acid sequence presented in SEQ ID NO:2 wherein said polypeptide binds TRAIL."")).

¹² 37 C.F.R. § 41.201 ("Involved claim means, for the purposes of 35 U.S.C. 135(a), a claim that has been designated as corresponding to the count.").

¹³ D.I. 22, Ex. C at 4:13-14.

¹⁴ D.I. 22, Ex. C at 4:15.

¹⁵ See D.I. 22, Ex. C. Summaries of the Board's determinations on the parties' motions are recited in the order those motions were addressed in the Board's motions decision rather than sequentially with reference to the numbered title of each motion.

¹⁶ Proposed count 2 reads: "A purified TRAIL-R polypeptide comprising an amino acid sequence that is at least 90% identical to the amino acid sequence presented in SEQ ID NO:2 wherein said polypeptide binds TRAIL *or induces apoptosis*." D.I. 22, Ex. C at 4:26-5:2 (emphasis added).

¹⁷ D.I. 22, Ex. C at 7:9. As a result of the Board's denial of HGS' substantive motion 1, the Board dismissed as moot, Immunex's responsive motion 4 which sought to be accorded benefit for the purpose of priority the filing dates of several U.S. applications contingent upon the grant of HGS substantive motion 1. D.I. 22, Ex. C at 7:11-18.

substantive motion 1, as to its proposed count 2.¹⁸ The Board dismissed as moot the motion to the extent it was contingent upon the grant of HGS' substantive motion 1.¹⁹ Immunex did not dispute HGS' claim to benefit for the purposes of priority the filing date of the '021 application and the Board accorded such benefit as to Count 1.²⁰ With regard to the '846 application, the Board determined that it did not describe an enabled embodiment within the scope of Count 1 and, therefore, that HGS was not entitled to benefit for the purpose of priority the filing date of that application as to Count 1.²¹

In Immunex's substantive motion 3, it moved for judgment that all of HGS' involved claims were unpatentable under 35 U.S.C. § 102(a) and/or (e) as anticipated by one or more of four cited references ("the Immunex references"). The Board determined that none of the Immunex references qualify as prior art under § 102(a) with regard to HGS' involved claims and denied Immunex's motion for judgment of anticipation under that section of the patent statute. One of the Immunex references, the '047 patent issued based on the '036 application, which was filed on June 26, 1997. Because that date is prior to the March 17, 1998 filing date of HGS' involved claims, the Board stated that the '036 application *prima facie* qualifies as prior art under § 102(e) against HGS' claims at issue. HGS did not

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¹⁸ D.I. 22, Ex. C at 7:20-8:2.

¹⁹ D.I. 22, Ex. C at 8:3-5.

²⁰ D.I. 22, Ex. C at 10:24-27.

²¹ D.I. 22, Ex. C at 28:7-9; 28:19-20.

²² D.I. 22, Ex. C at 29:2-10.

²³ D.I. 22, Ex. C at 31:20-32:1.

²⁴ D.I. 22, Ex. C at 32:13-18. In light of the '036 application being prior art, the Board determined it was unnecessary to consider whether HGS' involved claims were anticipated by two of the other Immunex references. D.I. 22, Ex. C at 32:18-20. The Board also found that Immunex had not established that the fourth of its cited references qualified as prior art under § 102(e) and denied Immunex's motion as to that

contest that the '047 patent describes the subject matter of its claims at issue. Instead, HGS argued that the '047 patent is not prior art because its '583 application is entitled to benefit of the March 17, 1997 filing date of its '846 application. Immunex argued that HGS was not entitled to benefit of the filing date of the '846 application due to a lack of utility.²⁵ The Board determined that the disclosure of the '846 application does not satisfy the "how-to-use" requirement of § 122, first paragraph, as to the subject matter of HGS' claims at issue and, therefore, those claims were not entitled to § 119(e) benefit of the filing date of the '846 application. Consequently, the Board found that Immunex's '047 patent qualified as § 102(e) prior art and that HGS' claims at issue were unpatentable under § 102(e) as anticipated by that patent.²⁶

In Immunex's substantive motion 2, it sought to redefine the scope of the interference by designating HGS claims 46, 55, 64, 64, 110 and 118 of the '842 application as corresponding to Count 1.²⁷ The Board denied that motion.²⁸

In Immunex's substantive motion 1, it sought to be accorded benefit for the purpose of priority the filing dates of four applications filed prior to the June 26, 1997 filing date of its '036 application to which the Board had already accorded that benefit.²⁹ The Board granted Immunex's motion as to two of the applications³⁰ and

reference. D.I. 22, Ex. C at 32:3-11.

²⁵ D.I. 22, Ex. C at 33:4-10. The Board noted that benefit for the purposes of antedating prior art under 35 U.S.C. § 119(e) is different from benefit for the purpose of priority. D.I. 22, Ex. C at 33:25-34:1.

²⁶ D.I. 22, Ex. C at 37:30-38:5.

²⁷ D.I. 22, Ex. C at 38:19-21.

²⁸ D.I. 22, Ex. C at 42:3.

²⁹ D.I. 22, Ex. C at 42:5-14.

³⁰ D.I. 22, Ex. C at 49:5-6; 57:9-12 (granting Immunex's substantive motion 1 as to application 08/869,852 (filed June 4, 1997) and application 08/829,536 (filed March 28, 1997)).

denied its motion as to the other two.31

In HGS' substantive motion 3, it sought judgement that all of the involved claims of Immunex's '358 patent were unpatentable under 35 U.S.C. § 102(e) as anticipated by U.S. Patent 6,872,568 ("HGS' '568 patent"). HGS' '568 patent issued from application 09/565,009 ("the '009 application"), filed May 4, 2000. The '009 application was said to be a continuation-in-part of application 09/042,583 ("the '583 application") filed March 17, 1998. When the '583 application was filed, Immunex claimed benefit under 35 U.S.C. § 119(e) to the '846 and '021 provisional applications filed March 17, 1997 and July 29, 1997, respectively. Immunex's '358 patent issued from the '392 application, filed May 25, 2000, after the filing of the '009 application. On its face, therefore, HGS' '568 patent is prior art to Immunex's involved claims. However, each party contended that their respective patents were entitled to benefit of the filing dates of several earlier applications.

The Board determined that, for prior art purposes, HGS' '568 patent was entitled to the May 4, 2000 filing date of the '009 application, but not to the earlier filing dates of the '583 parent application or the '021, or '846 provisional applications.³⁷ The Board also determined that, the involved claims of Immunex's '358 patent were at least entitled to benefit of the June 26, 1997 filing date of its

³¹ D.I. 22, Ex. C at 56:19-20 (denying Immunex's substantive motion 1 as to application 08/799,861 (filed February 13, 1997) and application 08/815,255 (filed March 12, 1997)).

³² D.I. 22, Ex. C at 57:14-17.

³³ D.I. 22, Ex. C at 57:19-58:4.

³⁴ D.I. 22, Ex. C at 58:5-6.

³⁵ D.I. 22, Ex. C at 58:18-21.

³⁶ D.I. 22, Ex. C at 58:21-23.

³⁷ D.I. 22, Ex. C at 61:21-62:2; 63:24-26.

'036 application.³⁸ Based on those determinations, HGS' '568 patent was not § 102(e) prior art as to Immunex's involved claims and the Board therefore denied HGS' substantive motion 3.³⁹

In Immunex's miscellaneous motion 5, it sought to exclude certain portions of the testimony HGS witnesses Dr. John C. Reed and Dr. Andrew Badley.⁴⁰ The Board determined that Immunex's arguments concerning Reed's testimony went to the weight to be accorded his testimony rather than its admissibility. Furthermore, because Reed's challenged testimony was not relied upon to Immunex's detriment in the Board's decisions on the motions where his testimony was considered, the Board dismissed as moot Immunex's motion with regard to that testimony.⁴¹ The Board also dismissed as moot Immunex's motion with regard to the challenged testimony of Badley for similar reasons.⁴²

Finally, in HGS' miscellaneous motion 4, it sought to exclude from evidence: certain exhibits related to Immunex's priority statements in the '381 Interference and two related interference proceedings; and certain testimony of Immunex witnesses Dr. Gavin R. Screaton (in a related interference), Norman Boiani, and Dr. Genchong Cheng.⁴³ The Board denied HGS' motion for failure to make a timely objection as to certain evidence; for seeking to exclude evidence which was either not part of the '381 Interference record or that had not been relied upon by Immunex; and/or

³⁸ D.I. 22, Ex. C at 64:5-7. The Board also noted that HGS did not dispute Immunex's claim to benefit of the '036 application's filing date. D.I. 22, Ex. C at 64:7-8.

³⁹ D.I. 22, Ex. C at 64:10-19.

⁴⁰ D.I. 22, Ex. C at 64:21-65:16.

⁴¹ D.I. 22, Ex. C at 65:22-66:9.

⁴² D.I. 22, Ex. C at 66:10-67:5.

⁴³ D.I. 22, Ex. C at 67:7-14.

because HGS' argument went to the weight to be accorded certain testimony rather than its admissibility.⁴⁴

Following the Board's March 26, 2007 decision on the parties' motions, HGS requested reconsideration of the part of that decision, on Immunex's substantive motion 3, holding its involved claims unpatentable under 35 U.S.C. § 102(e). HGS argued that a decision on that motion should have been deferred rather than decided on the merits.⁴⁵

The Board explained that interferences are typically conducted in two phases: a motions phase and the priority phase and noted that the parties filed several motions during the first phase of the interference.⁴⁶ Among those motions was HGS' substantive motion 2 (asserting demonstration of constructive reduction to practice by the filing of the '846 provisional application and arguing entitlement to the filing date of that application) and Immunex's substantive motion 3 (asserting, *inter alia*, that HGS' involved claims were anticipated by certain prior art under 35 U.S.C. § 102(e) and that HGS was not entitled to benefit of the filing date of the '846 application).⁴⁷

The Board noted that:

During his rebuttal period at oral argument, HGS' counsel requested for the first time in the interference that, in the event that HGS was held not to be entitled to the benefit of the earlier application, the decision on Immunex's Motion 3 be deferred until the priority phase of

⁴⁴ D.I. 22, Ex. C at 68:38-73-15.

⁴⁵ D.I. 22, Ex. G at 2:1-4 (Decision - Rehearing - Bd.R. 125(c)).

⁴⁶ D.I. 22, Ex. G at 2:8-3-5.

⁴⁷ D.I. 22. Ex. G at 3:4-27.

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As recited above, the board granted Immunex's substantive motion 3 to the extent that HGS' involved claims were anticipated under 35 U.S.C. § 102(e) and that HGS was not entitled under 35 U.S.C. § 119 to the filing date of the '846 provisional application. The Board also denied HGS' substantive motion for the priority benefit of the filing date of that application as to the subject matter of the count. The Board's opinion did not address HGS' request to defer decision on Immunex's motion.⁴⁹

In its reconsideration motion, HGS argued that the Board overlooked its oral argument request that it defer decision on Immunex's motion until the priority phase. The Board distinguished issues which warranted deferral in *LaVeen* from those implicated in the '381 Interference. The Board stated that the similarities in antedating under 37 C.F.R. § 1.131 and proving priority under 35 U.S.C. § 102(g) meant that there could be overlapping proofs on issues and, therefore, deferral of decision until the priority phase might prove less costly and more efficient for the parties and the Board. The Board declined to extend the *LaVeen* procedure where, as here, the opponent of a motion attempts to antedate by relying on the filing dates of earlier applications under 35 U.S.C. §§ 119 and 120. "Unlike antedating under § 1.131 and priority, which involve similar considerations, there are

⁴⁸ D.I. 22, Ex. G at 4:1-6. HGS relied upon *LaVeen v. Edwards*, 57 USPQ2d 1416 (BPAI 2000) as purportedly permitting such deferral. The Board noted that *LaVeen* "is an expanded panel decision and binding precedent of the Trial Division." D.I. 22, Ex. G at 5:2-3.

⁴⁹ D.I. 22, Ex. G at 4:15-23.

⁵⁰ D.I. 22, Ex. G at 4:25-27.

⁵¹ D.I. 22, Ex. G at 5:27-6:17

no readily apparent similarities between proofs and arguments attempting to establish an earlier effective filing date, on the one hand, and priority proofs and arguments, on the other."⁵²

Moreover, the Board stated that HGS' request for deferral of the motion (during its rebuttal at oral argument) was untimely. As set forth in *LaVeen*, when a party faces an unpatentability motion relying on § 102(a) or (e) prior art its choices are to (1) request deferral or (2) file an opposition. The Board noted that HGS filed an opposition and "at [that] point the issue was joined and there was no apparent reason to defer the decision to the priority phase. Having made this litigation choice, HGS, in effect [was] . . . requesting a second opportunity to antedate relying on what apparently would be § 1.131 antedating proofs."⁵³

Finding no reason to have deferred its decision on Immunex's motion the Board determined that it was appropriate to have decided that motion.

Consequently, it denied HGS' motion for reconsideration.⁵⁴

On June 1, 2007, HGS "was put under an order to show cause why this interference should be allowed to continue and judgment should not be entered against it" in light of the Board's prior determinations that "HGS was a junior party

⁵² D.I. 22, Ex. G at 7:17-20. The Board also noted that "considerations involved with an opposition asserting that the claims are entitled to an earlier effective filing date under §§ 119 and 120 may be similar to those involved in a motion asserting that the subject matter of a count should be accorded benefit of the filing date of an earlier application. For example, some proofs and testimony for the former may overlap the proofs and testimony for the later. Thus, both should be decided in the same phase of the interference." D.I. 22, Ex. G at 7:21-27.

⁵³ D.I. 22, Ex. G at 8:9-18. The Board also noted that Immunex's unpatentability motion was fully developed and ripe for decision and HGS had a full opportunity to address the unpatentability issue. D.I. 22, Ex. G at 9:5-9.

⁵⁴ D.I. 22, Ex. G at 9:9-10; 10:2.

applicant with all its claims corresponding to the count [were] unpatentable"⁵⁵
The Board framed the issue as "whether this interference should continue for the sole purpose of allowing a junior party with unpatentable claims to attempt to take away senior party Immunex's patent."⁵⁶ In response, "HGS [made] two principal arguments: (1) that the board is statutorily obligated to decide priority of invention and (2) that HGS will prevail on priority."⁵⁷

HGS' first argument relied on 35 U.S.C. § 135(a) which recites: "[t]he Board of Patent Appeals and Interferences shall determine questions of priority of the inventions and may determine questions of patentability." Citing two decisions of the Federal Circuit and a decision of the PTO Board, HGS argued that the language of § 135(a) mandates that the Board make a priority determination. The Board found that the decisions relied upon by HGS in support of that argument did not compel the board to determine priority under the facts of the '381 Interference.

The Board noted that *Perkins* related to an interference conducted under earlier interference rules during which both priority and patentability issues had been fully briefed by the parties and testimony had been submitted and cross-examined. Therefore, a fully developed record existed upon which the *Perkins* board made its decision. There, the Federal Circuit rejected an appeal by the senior party, which argued that after the *Perkins* board determined that the junior party's claims were

⁵⁵ D.I. 22, Ex. D at 2:1-3; 3:6-7.

⁵⁶ D.I. 22, Ex. D at 3:17-19.

⁵⁷ D.I. 22, Ex. D at 3:20-22.

⁵⁸ The decisions relied upon by HGS were *Perkins v. Kwon*, 886 F.2d 325 (Fed. Cir. 1989); *Rexam Indus. Corp. v. Eastman Kodak Co.*, 182 F.3d 1366 (Fed. Cir. 1999), and *Short v. Punnonen*, 82 USPQ2d 1382 (BPAI 2006). *See* D.I. 22, Ex. D at 4:6-9.

⁵⁹ D.I. 22, Ex. D at 4:10-11.

unpatentable any question of priority was moot. As a result, the senior party maintained that the interference should have been terminated with a judgment against the junior party without considering any question of priority. The Board in the instant case stated the issue in *Perkins* was whether the *Perkins* board had the authority to decide priority where the opponent's involved claims were held to be unpatentable, not whether § 135(a) compels a priority determination.⁶⁰

As with *Perkins*, the Board pointed out that *Rexam*, involved an assertion that the priority issue should not be reached because of mootness. In an interference between Rexam and Kodak, the *Rexam* board determined that Kodak proved an earlier constructive reduction to practice and priority was decided in its favor.

Thereafter, Rexam sought review under 35 U.S.C. § 146. During the pendency of that § 146 action, Kodak lost the right to its claimed subject matter as the result of a priority decision in a separate interference. In the § 146 action, Rexam contended that because Kodak had lost the right to its claimed subject matter in another interference, it should not be able continue to assert priority as to Rexam in the district court. The question was certified for an interlocutory appeal by the district court and the Federal Circuit rejected Rexam's argument. The Board in the instant action noted that, like *Perkins*, the issue of whether the *Rexam* board was

⁶⁰ D.I. 22, Ex. D at 4:17-5:19. The Board also noted that, subsequent to *Perkins*, the Federal Circuit clarified the holding of that case, and others, frequently cited as requiring that the Board reach a certain issue in an interference when it stated: "'Those cases . . . do not hold that *all* issues relating to patentability that are fairly raised in an interference *must* be addressed by the Board. Rather, those cases stand for the proposition that if, in a properly declared interference, an issue of priority or patentability is fairly raised and fully developed on the record, then the Board has the *authority* to consider that issue even after the Board determines that one party was not entitled to its claims." D.I. 22, Ex. D at 5:24-32 (quoting *Berman v. Housey*, 291 F.3d 1345, 1352 (Fed. Cir. 2002) (emphasis in original)).

compelled to make a priority determination was not before the court because during the underlying interference priority *had been* decided.⁶¹

Thus, contrasting the facts of *Perkins* and *Rexam*, the Board noted that, unlike those cases, the priority case in the '381 Interference was not fully developed and that Immunex's involved claims were not facially invalid.⁶²

The Board stated that the final decision relied upon by HGS for its contention that § 135(a) compelled the Board to make a priority determination was another case involving priority mootness. In Short, the junior party patentee informed the board that he would not filed a priority case, instead, he asserted that the senior party's involved claim was unpatentable and that the interference should be dissolved. The Short board had previously denied the junior party's unpatentability motion. As a result of that denial, the APJ gave the junior party an opportunity to file a priority motion or face an immediate judgment. In distinguishing Short, the Board stated that "[r]eminding Short of the necessity of putting on a priority case was necessary since senior party Punnonen's claims were patentable and Short's patent was facially invalid. As the junior party, Short was presumptively the second inventor and the Short's claims were invalid unless priority was established."63 The Board noted that, unlike the junior party Short (whose claims were facially invalid because he was not the first inventor by virtue of a later filing date), Immunex's patent is not facially invalid since senior party Immunex is the presumptive first

⁶¹ D.I. 22, Ex. D at 6:9-7:31.

⁶² D.I. 22, Ex. D at 9:5-10.

⁶³ D.I. 22, Ex. D at 8:1-9:3.

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HGS also argued that a patentability decision under § 102(e) is not a threshold issue and HGS had not waived putting on a priority case. The Board noted that neither argument addressed the basis for its order to show cause, "[t]he basis for the order was, that the critical question of the interference has been answered and there is no longer a sufficient reason to continue the interference and put the board and the parties to the expense of presenting and evaluating priority."⁶⁵

HGS also argued that it would prevail on priority and that it had filed its priority evidence.⁶⁶ In response to that argument, the Board stated:

HGS . . . fails to explain why we should evaluate the priority case of a junior party applicant without patentable interfering claims. . . . Immunex's patent is senior to HGS'. Immunex's claims also withstood HGS' unpatentability challenge during the motions phase. Stopping the interference at this point before the record on priority is fully developed would not leave a "facially invalid" patent. The question whether the Director can issue a patent on HGS['] involved application has been answered. While there is a strong public interest in resolving patent validity, resolving the validity of an issued patent is not the goal of an interference proceeding. The purpose of the interference is to resolve who between rivals of the same patentable invention should obtain the patent. It has been determined in this interference that HGS' involved claims are unpatentable over prior art. So the determination has been made that HGS is not entitled to a patent. And senior party Immunex's patent is not facially invalid. There is no significant need to address priority.⁶⁷

The Board determined that HGS did not provide sufficient reason to continue

⁶⁴ D.I. 22, Ex. D at 9:11-14.

⁶⁵ D.I. 22, Ex. C at 9:15-23.

⁶⁶ The Board noted that the submission by HGS of its priority evidence was premature and in contravention of the Boards order scheduling the events in the priority phase and that the Board declined to consider that evidence. See D.I. 22, Ex. D at 10:20-22; 11:11-12; 11:11-12 & n.3.

⁶⁷ D.I. 22, Ex. D at 10:23-11:10.

the interference and it issued a judgment against HGS.⁶⁸

GOVERNING LAW

HGS filed this action, pursuant to 35 U.S.C. § 146, for review of the July 27, 2007 judgment entered by the Board in the '381 Interference. Section 146 recites, in part:

Any party to an interference dissatisfied with the decision of the Board of Patent Appeals and Interferences on the interference, may have remedy by civil action In such suits the record in the Patent and Trademark Office shall be admitted on motion of either party . . . without prejudice to the right of the parties to take further testimony. The testimony and exhibits of the record in the Patent and Trademark Office when admitted shall have the same effect as if originally taken and produced in the suit. 69

As to what issues the district court can consider, the Federal Circuit noted that although § 146:

provides that the administrative record developed at the PTO may be admitted "without prejudice to the right of the parties to take further testimony," the right to offer new evidence is not unlimited. Rather, an action under § 146 is essentially a proceeding to review the action of the Board. While the expression "de novo" is often used to describe a § 146 action, the statute does not use this language or state that new

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⁶⁸ D.I. 22, Ex. D at 12:5-6. On the same date it issued its decision on the order to show cause, July 27, 2007, the Board issued an order stating that "[a] decision on the order to show cause and a judgment has been concurrently entered in this interference. All outstanding issues are therefore moot." D.I. 22, Ex. E at 1:1-3 (Order - Expunging Paper - BC.R.7(a)). The Board stated that "[HGS] has prematurely filed its evidence in support of priority on June 18, 2007. That evidence was not to be filed until Time Period 18, January 11, 2008." D.I. 22, Ex. E at 2:1-3. Because HGS' filing was premature and because the interference was terminated by judgment without considering priority, the Board ordered that HGS' priority record be expunged from the official PTO record. D.I. 22, Ex. E. at 3:6-9.

Federal Circuit pursuant to 35 U.S.C. § 141. In a section 141 action, however, further testimony is not permitted and the Federal Circuit reviews the Board's decisions solely based on the record before the Board. See General Instrument Corp. v. Scientific-Atlanta, Inc., 995 F.2d 209, 212 (Fed. Cir. 1993) ("A party dissatisfied with the Board's decision . . . may seek judicial review by proceeding directly to the United States Court of Appeals for the Federal Circuit for review based on the record before the Board. 35 U.S.C. §§ 141 -144 (1988). Alternatively, a party may proceed to a district court for a hybrid appeal/trial de novo proceeding in which the PTO record is admitted on motion of either party, but it may be supplemented by further testimony. 35 U.S.C. § 146.").

issues can freely be raised. Section 146 authorizes the district court on review to accept new testimony, but normally only as to issues raised by the parties during the proceedings below or by the Board's decision.⁷⁰

A section 146 action "is essentially a proceeding to review the action of the Board"⁷¹ and although the district court may hear new evidence on an issue presented to the Board, such action "is not a chance for a party to reconstruct its case, based on a new litigation strategy, leapfrogging the administrative process in the PTO."⁷²

Regarding whether an issue has been raised adequately during an interference so that the district court can review that issue, the Federal Circuit has stated that:

In order for an issue to be raised adequately in an interference proceeding so that it qualifies for evidentiary review in a section 146 proceeding, more is required than passing reference to the subject during the course of the interference proceeding. For the most part, parties should raise issues in the manner clearly specified in the PTO's interference regulations, that is through preliminary motions, motions to correct inventorship, belated motions delayed for good cause or opposition to these motions.

Short of such compliance with the regulations, issues may only be

omitted).

⁷⁰ Conservolite, Inc. v. Widmayer, 21 F.3d 1098, 1102 (Fed. Cir. 1994) (citing Case v. CPC Int'l, Inc., 730 F.2d 745, 752 (Fed. Cir. 1984)); see also Winner Int'l Royalty Corp. v. Wang, 202 F.3d 1340, 1346 (Fed. Cir. 2000) (Section 146 "authorizes the district court to accept all proffered testimony on issues raised by parties during the proceedings below or by the board's decision.") (quoting Case, 730 F.2d at 752); General Instrument, 995 F.2d at 212 (Fed. Cir. 1993) ("[A] party may proceed to a district court for a hybrid appeal/trial de novo proceeding in which the PTO record is admitted on motion of either party, but it may be supplemented by further testimony[, pursuant to § 146].").

⁷¹ Boston Scientific Scimed, Inc. v. Medronic Vascular, Inc., 497 F.3d 1293, 1298 (Fed. Cir. 2007).

⁷² Conservolite, 21 F.3d at 1102; Boston Scientific Scimed, 497 F.3d at 1298 ("A party may not, however, advance new legal theories at the trial court level, even if the overarching legal issues was presented below."); *Id.* ("Failure to advance legal theories before the board constitutes a failure to 'make a complete presentation of the issues,' and permitting a party to raise those theories for the first time before the trial court would be both inefficient and 'wasteful of administrative and judicial resources."") (citation

deemed raised for section 146 purposes if the record clearly demonstrates that the issue was undeniably placed before the examiner-in-chief, and one or more parties insisted that the issue be resolved in the process of deciding which of the parties was entitled to priority.⁷³

Because a § 146 action is equitable in nature, however, the Federal Circuit has suggested that there are some instances where the district court may consider issues that were not raised during the interference.⁷⁴ With regard to an issue that was raised before the Board, the Federal Circuit has not decided whether a district court could restrict admission of testimony on that issue.⁷⁵

DISCUSSION

First, Immunex argues that the issue of priority was not properly raised before the board and, therefore, the only issue on appeal with respect to priority is whether the Board abused its discretion in not considering the issue. It contends, therefore, that no discovery related to priority should be permitted. Next, Immunex maintains that no discovery should be permitted with regard to the motions decided by the Board.

HGS argues that a 146 action provides for complete review of the issues raised during an interference, including the first real opportunity for discovery. HGS

⁷³ General Instrument, 995 F.2d at 214; see also Conservolite, 21 F.3d at 1102 (citing General Instrument, 995 F.2d at 214).

⁷⁴ General Instrument, 995 F.2d at 214 ("District court review of an interference proceeding under section 146 is an equitable remedy of longstanding. As such, the district court may, in appropriate circumstances, exercise its discretion and admit testimony on issues even though they were not raised before the Board.").

⁷⁵ *Id.* ("[W]e again have no occasion to decide whether 'a district court may properly restrict the admission of testimony on an issue raised before the board.") (quoting *Case*, 730 F.2d at 752). The district court has discretion in its decision to admit evidence in a § 146 action. *See Winner*, 202 F.3d at 1351 ("A district court's decision to admit or exclude evidence at trial is reviewed for abuse of discretion.") (citing *Conservolite*, 21 F.3d at 1303).

makes three overarching responses to Immunex's arguments. First, it argues that Immunex incorrectly contends that the scope of review in a § 146 action is limited to issues decided by the Board. HGS maintains that the proper scope of review encompasses not only issues decided by the Board but, also, those issues raised in an interference. Second, HGS contends that, procedurally, the issues raised by Immunex should be presented to the court (as well as questions concerning the admissibility of evidence on those issues) are appropriately considered in the context of formal motions *in limine*, rather than in the context of establishing a scheduling order. Third, HGS argues that if Immunex seeks to limit discovery, the proper route for it to do so is to object to discovery requests when they are made, under Fed. R. Civ. P. 34(b), or to move for a protective order, under Fed. R. Civ. P. 26(c).

HGS is correct that this court's § 146 review is not limited to issues decided by the Board and Immunex acknowledges that in its submission.⁷⁶ As to HGS' second and third arguments, it is more efficient for both the parties and the court to address the scope of review and appropriate discovery (to the extent possible) at this stage of the litigation.

With regard to whether the issue of priority is subject to review in this action, the court finds that the issue was raised adequately below and that it is subject to this court's review. In the interference below, the priority phase had begun prior to

⁷⁶ See D.I. 22 at 3 ("An issue may not be appealed under § 146 unless the issue was decided by the Board *or raised by the parties during the proceedings below.*") (citing *Conservolite*, 21 F.3d at 1100) (emphasis added); *id.* at 2 ("The Court cannot consider issues *not raised* before the Board and should not address issues *not decided* by the Board. Discovery should be limited accordingly.") (emphasis added).

the Board's termination of the interference. HGS had filed a motion on priority prior to that termination.⁷⁸ The issue of priority, therefore, was not merely a "passing reference to the subject during the course of the interference proceeding."⁷⁹ Although HGS prematurely filed its priority evidence in support of its motion, HGS represents that its motion was properly filed with the Board. 80 While Immunex's opposition and evidence in response to that motion (and any reply by HGS) were not submitted prior to the Board's termination of the interference, HGS' request for reconsideration of the Board's motions decision and its response to the order to show cause clearly demonstrate that "one or more parties insisted that the issue be resolved."81 The court does not view the fact that HGS is seeking consideration of the priority issue in this court "reconstruct[ing] its case, based on a new litigation strategy, [or] leapfrogging the administrative process of the PTO."82 While "[a] party may not . . . advance new legal theories at the trial court level,"83 HGS represents that it is not planning to do so. "HGS is seeking review on priority based on legal theories set forth in its Motion 7."84

The court also notes "[t]he public interest in ensuring that only those patents

⁷⁷ See D.I. 22 at 2 ("The Board . . . entered judgment adverse to HGS on July 27, 2007, *three weeks after the priority phase was initiated* and seven months before the priority phase was set to end.") (emphasis added).

⁷⁸ See D.I. 24 at 7 ("HGS properly filed a motion on priority (Motion 7). HGS had previously obtained the Board's permission to file that motion and to supplement it.").

⁷⁹ General Instrument, 995 F.2d at 214.

⁸⁰ *Id.* ("In order for an issue to be raised adequately in an interference proceeding so that it qualifies for evidentiary review in a section 146 proceeding . . . parties should raise issues in the manner clearly specified in the PTO's interference regulations").

⁸¹ *Id*.

⁸² Conservolite, 21 F.3d at 1102.

⁸³ Boston Scientific Scimed, Inc. v. Medronic Vascular, Inc., 497 F.3d 1293, 1298 (Fed. Cir. 2007).

⁸⁴ D.I. 24 at 7 (emphasis added).

that claim patentable subject matter are issued and maintained."⁸⁵ Notwithstanding the Board's determination not to decide the issue, consideration of priority in this action may serve that interest. Consequently, the court will consider the priority issue and the parties may conduct discovery on that issue. Disputes, if any, that arise from discovery may be submitted to the court pursuant to the appropriate Federal Rule of Civil Procedure, and consistent with the court's scheduling order.

With regard to the court's review of the Board's decisions on the parties motions during the first phase of the interference, Immunex does not dispute that those decisions are subject to review by this court. Instead, it argues that no additional discovery should be permitted as to the issues presented by those decisions "because the legal theories on appeal are limited to either HGS' own information or the objective disclosure of an Immunex or HGS patent reference."

HGS notes the acknowledgment by Immunex that the motions decided by the Board are subject to the court's review, but strongly disagrees with its contention that no discovery is appropriate on any of those issues. HGS stresses that a § 146 action "provides for a complete review of the issues raised during an interference, including the first real opportunity for discovery" and that "[t]he fundamental purpose of a § 146 action . . . is to allow the parties to complete the record by taking further

⁸⁵ Rexam Indus. Corp. v. Eastman Kodak Co., 182 F.3d 1366, 1370 (Fed. Cir. 1999). The court notes that in connection with the above quote that the Federal Circuit spoke of "issues of priority and patentability that have been raised and fully developed." Id. (emphasis added). Immunex may argue that because it did not file an opposition, and supporting evidence, to HGS' priority motion, that the priority issue was not fully developed. The court believes, however, that, under the facts of this case, the language of General Instrument and Conservolite regarding when an issue is raised adequately during an interference to support district court review demonstrates that consideration of the priority issue is appropriate.

⁸⁶ D.I. 22 at 1.

discovery."87 HGS argues that "[s]ection 146 authorizes the district court to allow all discovery within the confines of Federal Rule of Civil Procedure 26, and virtually all § 146 cases, including those cited by Immunex, have allowed liberal discovery."88 HGS maintains that Immunex "conflates the constraints on admissibility with those on discoverability."89 HGS contends that under Fed. R. Civ. P. 26(b)(1), parties to a § 146 action, as with all civil actions, are "entitled to obtain discovery of all relevant evidence, as well as evidence 'reasonably calculated to lead to the discovery of admissible evidence,' even if such evidence is not admissible at trial."90 HGS, therefore, urges this court to permit discovery to proceed and rule on the admissibility, or discoverability, of certain evidence at a later date.

HGS also argues that "when compelling circumstances present themselves, the district court can even consider *entirely new* issues never raised before the Board."⁹¹ The court notes that the *Conservolite* court listed examples of appropriate circumstances under which the district court might consider such issues "have been said to include an intervening change in the law, the presence of a new issue, or the admission of other new evidence deserving of a response or further elaboration."⁹²

⁸⁷ D.I. 24 at 1, 4.

⁸⁸ D.I. 24 at 4-5 (footnote omitted).

⁸⁹ D.I. 24 at 5.

⁹⁰ D.I. 24 at 5 (quoting Fed. R. Civ. P. 26(b)(1)).

⁹¹ D.I. 24 at 2 (emphasis in original) (citing *Conservolite, Inc. v. Widmayer*, 21 F.3d 1098, 1102 (Fed. Cir. 1994)).

relating to the interference proceeding itself may be one such issue" where a district court might hear an issue not raised before the Board. *General Instrument Corp. v. Scientific-Atlanta, Inc.*, 995 F.2d 209, 214 (Fed. Cir. 1993) (citing *Standard Oil Co. v. Montedison S.p.A*, 540 F.3d 611, 616-17 (3d Cir. 1979)). When determining whether to exercise its discretion to consider issues not raised during an interference, "courts have considered whether there was suppression, bad faith, or gross negligence on the part of the plaintiff in failing to raise an issue before the Board; whether the evidence was then reasonably available; and whether the issue has been or may be more conveniently or expeditiously raised in another judicial

The court believes that, at this stage of the litigation, Immunex's request that the court issue a blanket order precluding any discovery on the issues raised during the interference is unduly broad. Under Fed. R. Civ. P.26(b)(1), "[p]arties may obtain discovery regarding any matter, not privileged, that is relevant to a claim or defense of that party. . . . Relevant information need not be admissible at trial if the discovery appears reasonably calculated to lead to the discovery of admissible evidence." In Winner Int'l Royalty Corp. v. Wang, 93 the Federal Circuit considered the question of whether the district court had abused its discretion in allowing, inter alia, the presentation of documents and testimony pertaining to the nexus required to show commercial success. The challenger acknowledged that the commercial success issue had been raised during the interference, but argued that, because the subsidiary nexus issue was not, that subsidiary issue could not be raised before the district court. In determining the district court had not abused its discretion in considering the nexus issue, the Federal Circuit stated that evidence related to that issue "is at least relevant to the issue of commercial success before the Board."94 The court notes that it was the *relevance* of the evidence in dispute which the Federal Circuit considered, not whether that discovery on the issue was improper in

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proceeding. Other courts have applied a test of due diligence in identifying and procuring evidence, whether or not the failure to identify or procure the evidence was attended by bad faith motives or for tactical reasons." *Conservolite*, 21 F.3d at 1102 (citations omitted).

^{93 202} F.3d 1340 (Fed. Cir. 2000).

⁹⁴ Winner, 202 F.3d at 1351 (emphasis in original); see also Estee Lauder Inc. v. L'Oreal, S.A., 129 F.3d 588, 592 (Fed. Cir. 1997) (The Federal Circuit determined that the district court did not abuse its discretion in considering test data not presented during the interference as that evidence was relevant to priority of reduction to practice which issue was raised with the Board. The court stated, however, that, absent compelling circumstances, the district court could not consider that evidence with regard to "any other issue not raised before the board, such as priority based on prior conception coupled with diligent reduction to practice.").

the first instance.

Furthermore, in light of the Federal Circuit's silence on "whether a district court may properly restrict the admission of testimony on an issue raised before the board,"95 the court agrees with HGS that the parties should be permitted to take discovery "concerning any issue raised before the Board." Should a party believe that particular discovery is being sought on an issue that was not raised before the Board, or is otherwise improper, it may present the matter consistent with the scheduling order by which the court can consider such challenge on an issue-byissue basis. Proceeding in this manner will give the parties the ability explain the relevance, or lack thereof, for specific discovery requests. Determination of the admissibility of challenged evidence may be addressed at the appropriate time in the proper format.

April 8, 2008 Wilmington, Delaware

 $^{^{95}}$ General Instrument, 995 F.2d at 214 (internal quotation marks omitted) (emphasis added). 96 D.I. 24 at 9.